



PATENT  
Attorney Docket No. FORS-08167

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Molly Accola *et al.*

Serial No.: 10/606,577

Group No: 1634

Filed: 06/26/03

Examiner: Goldberg, J.

Entitled: CFTR Allele Detection Assays

INFORMATION DISCLOSURE  
STATEMENT TRANSMITTAL

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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By:

  
Mary Ellen Waite

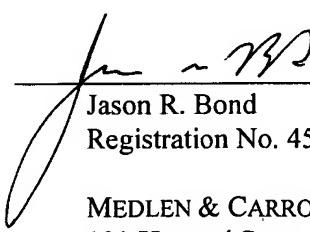
Sir or Madam:

Enclosed please find an Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

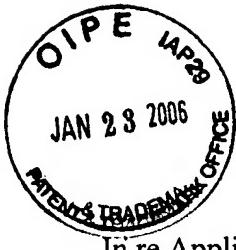
A check for \$180.00 is also enclosed pursuant to 37 C.F.R. § 1.17(p) for filing this Information Disclosure Statement after three months as set forth in C.F.R. § 1.97(c).

The Commissioner is hereby authorized to charge any additional fee or credit overpayment to our Deposit Account No. 08-1290. An originally executed duplicate of this transmittal is enclosed for this purpose.

Dated: January 20, 2006

  
Jason R. Bond  
Registration No. 45,439

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San Francisco, California 94105  
608/218-6900



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By:



Mary Ellen Waite

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The citations listed below may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

- U.S. Patent No. 5,614,402
- U.S. Patent No. 5,795,763
- U.S. Patent No. 5,843,669
- U.S. Patent No. 6,090,606
- U.S. Patent No. 6,090,543
- U.S. Patent No. 5,846,717

- U.S. Patent No. 5,985,557
- U.S. Patent No. 5,994,069
- U.S. Patent No. 6,001,567
- U.S. Patent No. 6,235,502
- U.S. Patent No. 6,194,149
- U.S. Patent No. 6,210,884
- U.S. Patent No. 6,183,960
- WO 98/23774
- WO 02/070755A2
- WO 01/90337A2
- WO 97/27214
- WO 98/42873
- WO9850403
- WO0198537
- Heim, et al., Genetics in Medicine 3(3):168-176 (2001)
- Raman, et al., Pediatrics 109(1): E13 (2002)
- Dumur, et al., Hum Genet 97: 7-10 (1996)
- Grody, Cutting, et al., Genetics in Medicine 3(2):149-154 (2001)
- Grody and Desnick, Genetics in Medicine 3(2):87-90 (2001)
- Rosenstein and Cutting, Journal of Pediatrics 132(4): 589-595 (1999)
- LeGrys, Laboratory Medicine 33(1): 55-57 (2002)
- Wilson, et al., Journal of Pediatrics 132 (4): 596-599 (1998)
- Gregg, et al., Pediatrics 99(6): 819-824 (1997)
- Rock, et al., Pediatrics 85(6): 1001-1007 (1990)
- Kerem, et al., Science 245: 1073-1080 (1989)
- Riordan, et al., Science 245: 1066-1073 (1989)
- Rommens, et al., Science 245: 1059-1065 (1989)
- Bobadilla, et al., Human Mutation 19: 575-606 (2002)
- Noone and Knowles, Respiratory Research 2(6):328-332 (2001)

- Rohlfs, et al., Genetics in Medicine 4(5):319-323 (2002)
- Kiesewetter, et al., Nature Genetics 5(3): 274-278 (1993)
- Fujimura, Northrup et al. N Engl J Med., Jan 4, 322(1):61 (1990)
- Lyamichev et al., Nat. Biotech., 17:292 (1999)
- Hall et al., PNAS, USA, 97:8272 (2000)
- Reynaldo et al., J. Mol. Biol. 97: 511-520 (2000)

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: January 20, 2006

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PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 5

### Complete if Known

Application Number	10/606,577
Filing Date	06/26/2003
First Named Inventor	Accola et al.
Art Unit	1634
Examiner Name	Goldberg, J.
Attorney Docket Number	FORS-08167

### U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
1	US- 5,614,402	03/25/1997	Dahlberg et al.	whole document	
2	US- 5,795,763	08/18/1998	Dahlberg et al.	whole document	
3	US- 5,843,669	12/01/1998	Kaiser et al.	whole document	
4	US- 6,090,606	07/18/2000	Kaiser et al.	whole document	
5	US- 6,090,543	07/18/2000	Prudent et al.	whole document	
6	US- 5,846,717	12/08/1998	Brow et al.	whole document	
7	US- 5,985,557	11/16/1999	Prudent et al.	whole document	
8	US- 5,994,069	11/30/1999	Hall et al.	whole document	
9	US- 6,001,567	12/14/1999	Brow et al.	whole document	
10	US- 6,235,502	05/22/2001	Weissman et al.	whole document	
11	US- 6,194,149	02/27/2001	Neri et al.	whole document	
12	US- 6,210,884	04/03/2001	Lizardi	whole document	
13	US- 6,183,960	02/06/2001	Lizardi	whole document	
	US-				

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
14	WO 98/23774					
15	WO 02/070755A2					
16	WO 01/90337A2					
17	WO 97/27214					
18	WO 98/42873					
19	WO9850403					

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Sheet

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Sheet 2

of 15

Attorney Docket Number FORS-08167

## **U. S. PATENT DOCUMENTS**

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Sheet	3	of	5
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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	21	Heim, et al., Genetics in Medicine 3(3):168-176 (2001)	
	22	Raman, et al., Pediatrics 109(1): E13 (2002)	
	23	Dumur, et al., Hum Genet 97: 7-10 (1996)	
	24	Grody, Cutting, et al., Genetics in Medicine 3(2):149-154 (2001)	
	25	Grody and Desnick, Genetics in Medicine 3(2):87-90 (2001)	
	26	Rosenstein and Cutting, Journal of Pediatrics 132(4): 589-595 (1998)	
	27	LeGrys, Laboratory Medicine 33(1): 55-57 (2002)	
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	30	Rock, et al., Pediatrics 85(6): 1001-1007 (1990)	

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	31	Kerem, et al., Science 245: 1073-1080 (1989)		
	32	Riordan, et al., Science 245: 1066-1073 (1989)		
	33	Rommens, et al., Science 245: 1059-1065 (1989)		
	34	Bobadilla, et al., Human Mutation 19: 575-606 (2002)		
	35	Noone and Knowles, Respiratory Research 2(6):328-332 (2001)		
	36	Rohlf, et al., Genetics in Medicine 4(5):319-323 (2002))		
	37	Kiesewetter, et al., Nature Genetics 5(3): 274-278 (1993)		
	38	Fujimura, Northrup et al. N Engl J Med., Jan 4, 322(1):61 (1990)		
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